510(k) Summary

DEC 1 8 2002

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K011723.

SUBMITTER: Pi Medical, Inc.
2800 Patton Road
St. Paul, MN 55113

CONTACT PERSON: Edward W. Numainville

DATE PREPARED: December 17, 2002

TRADE NAME: Pi Medical Anti-Snoring Device

COMMON NAME: Anti-Snoring Device

CLASSIFICATION: 21 CFR Section 874, Ear, Nose & Throat Devices
Unclassified, as are the predicate devices

PRODUCT CODE: LRK

PREDICATE DEVICE(S): Influence, Inc.'s Repose Bone Screw System, cleared via 510(k) K981677 on August 27, 1999 for the treatment of obstructive sleep apnea and/or snoring.

Somnoplasty System, manufactured by Somnus Medical Technologies, Inc. and cleared via 510(k) K971450 on July 17, 1997 for reducing the severity of snoring in some individuals.

DEVICE DESCRIPTION: The Pi Medical Anti-Snoring Device is intended as a treatment option for snoring and consists of an implant and

a delivery tool. The Anti-Snoring Device is designed to stiffen the tissue of the soft palate and to reduce the dynamic flutter of those tissues without interfering with the normal function of the soft palate.

The implant is a cylindrical shaped segment of braided polyester filaments. The delivery tool is comprised of a handle and needle assembly that allows for positioning and placement of the implant submucosally in the soft palate. The implant is permanent while the delivery tool is disposable.

The implant is available in a range of lengths, 0.59" to 1.38" and three different diameters: 0.050", 0.064", and 0.087". Corresponding delivery tool sizes are: 16Ga, 14Ga and 12Ga. The different sizes allow the physician to tailor the size of the implant to the patient's anatomy.

INTENDED USE:

The Anti-Snoring Device is intended for use in stiffening the soft palate tissue which may reduce the severity of snoring in some individuals.

EQUIVALENCE TESTING:

The Anti-Snoring Device has been tested for dimensional integrity, mechanical performance and reliability, biocompatibility, insertion ability and preclinical performance. The Anti-Snoring Device met or exceeded all performance requirements.

CONCLUSION:

The Pi Medical Anti-Snoring Device is substantially equivalent to the Repose Bone Screw System (K981677) in its product code, intended use, design, materials and its use of a permanent implant to address snoring problems. In addition, the Anti-Snoring Device is substantially equivalent to the Somnoplasty System (K971450) in its intended use, target population, design, function, and approach to snoring management. Testing demonstrates the device performs as anticipated and raises no new questions of safety and effectiveness over the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2002

Mr. Edward W. Numainville
Vice President, Regulatory and Clinical Affairs
P I Medical, Incorporated
2800 Patton Road
Saint Paul, Minnesota 55113

Re: K011723
Trade/Device Name: Anti-Snoring Device
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LRK
Dated: October 25, 2002
Received: October 28, 2002

Dear Mr. Numainville:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

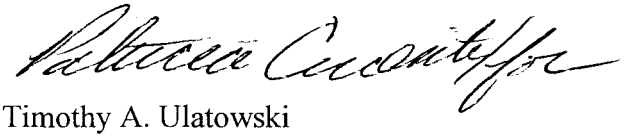
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011723

Device Name: **Anti-Snoring Device**

Indications For Use:

The Anti-Snoring Device is intended for use in stiffening the soft palate tissue which may reduce the severity of snoring in some individuals.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K011723